

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Resonium A.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Sodium Polystyrene Sulfonate 99.934% w/w.

3 PHARMACEUTICAL FORM

Buff coloured powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Resonium A is an ion-exchange resin that is recommended for the treatment of hyperkalaemia associated with anuria or severe oliguria. It is also used to treat hyperkalaemia in patients requiring dialysis and in patients on regular haemodialysis or on prolonged peritoneal dialysis.

4.2 Posology and method of administration

Resonium A is for oral or rectal administration only.

The dosage recommendations detailed in this section are a guide only; the precise requirements should be decided on the basis of regular serum electrolyte determinations.

Adults, including the elderly:

Oral

The usual dose is 15g three or four times a day. Each dose should be given as a suspension in a small amount of water or, for greater palatability, in syrup (but not fruit juices which contain potassium), in the ratio of 3 to 4ml per gram of resin.

Rectal

This route should be reserved for the patient who is vomiting or who has upper gastrointestinal tract problems, including paralytic ileus or it may be used simultaneously with the oral route for more rapid initial results. The resin may be given rectally as a suspension of 30g resin in 150ml of water or 10% dextrose, as a daily retention enema. In the initial stages administration by this route as well as orally may help to achieve a more rapid lowering of the serum potassium level.

The enema should if possible be retained for at least nine hours following which the colon should be irrigated to remove the resin. If both routes are used initially it is probably unnecessary to continue rectal administration once the oral resin has reached the rectum.

Children:

Oral

In smaller children and infants correspondingly smaller doses should be employed by using as a guide a rate of 1mEq of potassium per gram of resin as the basis for calculation. An appropriate initial dose is 1g/kg body weight daily in divided doses, in acute hyperkalaemia. Dosage may be reduced to 0.5g/kg of body weight daily in divided doses for maintenance therapy.

The resin is given orally, preferably with a drink (not a fruit squash because of the high potassium content) or a little jam or honey.

Rectal

When refused by mouth it should be given rectally, using a dose at least as great as that which would have been given orally, diluted in the same ratio as described for adults.

Following retention of the enema, the colon should be irrigated to ensure adequate removal of the resin.

Neonates:

Resonium A should not be given by the oral route. With rectal administration, the minimum effective dosage within the range 0.5g/kg to 1g/kg should be employed diluted as for adults and with adequate irrigation to ensure recovery of the resin.

4.3 Contraindications

- In patients with plasma potassium levels below 5mmol/litre.
- History of hypersensitivity to polystyrene sulfonate resins.
- Obstructive bowel disease.
- Resonium A should not be administered ***orally*** to neonates and is contraindicated in neonates with reduced gut motility (post-operatively or drug-induced).

4.4 Special warnings and precautions for use

Sorbitol: Gastrointestinal stenosis, intestinal ischemia and its complications (necrosis and perforation) may occur in patients treated with polystyrene sulfonate, especially in patients using sorbitol. Therefore concomitant use of Sorbitol with sodium polystyrene sulfonate is not recommended (see Section 4.5 Interactions and Section 4.8 Undesirable effects).

Hypokalaemia: The possibility of severe potassium depletion should be considered, and adequate clinical and biochemical control is essential during

treatment, especially in patients on digitalis. Administration of the resin should be stopped when the serum potassium falls to 5mmol/litre.

Other electrolyte disturbances: Because the resin may bind calcium and magnesium ions, deficiencies of these electrolytes may occur. Accordingly, patients should be monitored for all applicable electrolyte disturbances.

Other risks: In the event of clinically significant constipation, treatment should be discontinued until normal bowel movement has resumed. Magnesium-containing laxatives should not be used (see section 4.5 Interactions).

The patient should be positioned carefully when ingesting the resin, in order to avoid aspiration, which may lead to bronchopulmonary complications.

Children and neonates: In neonates, sodium polystyrene sulfonate should not be given by the oral route. In children and neonates particular care is needed with rectal administration as excessive dosage or inadequate dilution could result in impaction of the resin. Due to the risk of digestive haemorrhage or colonic necrosis, particular care should be observed in premature infants or low birth weight infants.

Patients at risk from an increase in sodium load: Care should be taken when administering to patients in whom an increase in sodium load may be detrimental (i.e. congestive heart failure, hypertension, renal damage or oedema). In such instances, adequate clinical and biochemical control is essential. The calcium form of the resin may have advantages in this situation.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use not recommended

Sorbitol (oral or rectal): Concomitant use of Sorbitol with sodium polystyrene sulfonate is not recommended due to cases of intestinal necrosis and other serious gastrointestinal adverse reactions, which may be fatal (see Section 4.4 Special warnings and Section 4.8 Undesirable effects).

To be used with caution

- Cation-donating agents: may reduce the potassium binding effectiveness of Resonium A.
- Non-absorbable cation-donating antacids and laxatives: There have been reports of systemic alkalosis following concurrent administration of cation-exchange resins and non-absorbable cation-donating antacids and laxatives such as magnesium hydroxide and aluminium carbonate.
- Aluminium hydroxide: Intestinal obstruction due to concretions of aluminium hydroxide has been reported when aluminium hydroxide has been combined with the resin.
- Digitalis-like drugs: The toxic effects of digitalis on the heart, especially various ventricular arrhythmias and A-V nodal dissociation, are likely to be exaggerated if hypokalaemia is allowed to develop. (See 4.4 Special warnings and special precautions for use).
- Lithium: Possible decrease of lithium absorption.

- Levothyroxine: Possible decrease of levothyroxine absorption.

4.6 Fertility, pregnancy and lactation

No data are available regarding the use of polystyrene sulfonate resins in pregnancy and lactation. The administration of Resonium A in pregnancy and during breast feeding therefore is not advised unless, in the opinion of the physician, the potential benefits outweigh any potential risks.

4.7 Effects on ability to drive and use machines

There are no specific warnings.

4.8 Undesirable effects

• Metabolism and nutrition disorders

In accordance with its pharmacological actions, the resin may give rise to sodium retention, hypokalaemia and hypocalcaemia, and their related clinical manifestations (see Section 4.4 Special warnings and Section 4.9 Overdose).

Cases of hypomagnesaemia have been reported.

• Gastrointestinal disorders

Gastric irritation, anorexia, nausea, vomiting, constipation and occasionally diarrhoea may occur. Faecal impaction following rectal administration particularly in children, and gastrointestinal concretions (bezoars) following oral administration have been reported. Gastrointestinal stenosis and intestinal obstruction have also been reported, possibly, due to co-existing pathology or inadequate dilution of the resin.

Gastrointestinal ischemia, ischemic colitis, gastro-intestinal tract ulceration or necrosis, which could lead to intestinal perforation have been reported which is sometimes fatal.

The majority of cases have been reported with concomitant use of Sorbitol (see Section 4.4 Special warnings and Section 4.5 Interactions).

• Respiratory, thoracic and mediastinal disorders

Some cases of acute bronchitis and/or broncho-pneumonia associated with inhalation of particles of sodium polystyrene sulfonate have been described.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

Biochemical disturbances from overdosage may give rise to clinical signs of symptoms of hypokalaemia, including irritability, confusion, delayed thought processes, muscle weakness, hyporeflexia and eventual paralysis. Apnoea may be a serious consequence of this progression. Electrocardiographic changes may be consistent with hypokalaemia; cardiac arrhythmia may occur. Hypocalcaemic tetany may occur. Appropriate measures should be taken to correct serum electrolytes and the resin should be removed from the alimentary tract by appropriate use of laxatives or enemas.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Resonium A is a cation exchange resin for the treatment of hyperkalaemia.

5.2 Pharmacokinetic properties

Ion exchange resins with a particle size ranging from 5 - 10 micrometres (as in Resonium A) are not absorbed from the gastro-intestinal tract and are wholly excreted in the faeces.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Resonium A also contains: saccharin and vanillin.

6.2 Incompatibilities

There are no specific incompatibilities.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

None stated.

6.5 Nature and contents of container

Supplied in HDPE containers with LDPE tamper evident closures containing 454g Resonium A together with a plastic scoop, which, when filled level, contains approximately 15g.

6.6 Special precautions for disposal

Refer to 4.2. Posology and method of administration.

7 MARKETING AUTHORISATION HOLDER

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2 April 2003

10 DATE OF REVISION OF THE TEXT

15 January 2014

LEGAL CLASSIFICATION

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